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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,549	08/03/2001	Jeffrey C. Rapp	AVI 013	1388

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EXAMINER
LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
1636	14

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,549	RAPP, JEFFREY C.	
	Examiner	Art Unit	
	Gerald G Leffers Jr.	1636	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-61* is/are pending in the application.

4a) Of the above claim(s) *34-36,40 and 45-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-33,37-39,41-44 and 58-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 2/11/03 as Paper No. 12, in which several claims were amended (claims 8, 17, 22, 29 and 58) and in which several claims were cancelled (claims 1-7).

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-33) in Paper No. 12, filed 2/11/03, is acknowledged. The traversal is on the ground(s) that recombining all of the groups would not require a burdensome search on the part of the examiner. This is not found persuasive because it ignores the different criteria cited by the examiner as to why searching all of the groups together would require a burdensome search. For example, an indication that two different groups have a different classification is all that need be shown in order to establish a burdensome search requirement for the examiner in examining the different inventions of different groups as part of one application.

Applicants' assertion that amended claims 58-61 should be included in Group I is accurate. Claims 58-61 have been placed in Group I and are under consideration. Upon further reconsideration, the requirement for election of one of SEQ ID NOS: 65-68 has been withdrawn.

Also, upon further consideration, claims directed towards an isolated cell *in vitro* comprising the nucleic acids of claims 1-33 (claims 37-39, 41-44) have been rejoined in Group I as well. This amounts to rejoinder of the invention of Group V and the invention of Group I (it is noted that the examiner inadvertently switched claims in Groups IV and V in Paper No. 10). The rationale for this decision is that cultured cells are routinely used for maintenance,

amplification and expression of constructs similar to those described in the instant specification and would be an obvious residence for the claimed cells. Also, the search requirement for cultured cells comprising the instant nucleic acids would not necessarily be burdensome. The embodiments of Group IV (i.e. eukaryotic cells within an animal comprising the nucleic acids of Group I) remain distinct from the rejoined claims for reasons of record in Paper No. 10. The non-patent literature search requirement for the *in vitro* embodiments is not coextensive with that for the *in vivo* embodiments (e.g. methods of delivery to cells in an animal, methods of making transgenic animals, etc.). Therefore, the invention of Group IV has not been rejoined with the invention of Group I.

Group I now comprises claims 8-33, 37-39, 41-44 and 58-61. Claims 34-36, 40, 45-57 are withdrawn from consideration as being directed to nonelected embodiments.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed 10/23/01 as Paper No. 3 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not provide a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the

time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following informalities: at several points in the specification the term "□2b" appears (e.g. page 55, line 21). It appears applicants may intend the term to recite "interferon α2b".

Appropriate correction is required wherever "□2b" appears in the instant specification.

Claim Objections

Claims 37-39, 42-44 are objected to because of the following informalities: the claims still read on nonelected embodiments (i.e. cells in an animal). It would be remedial to amend the cited claims to make clear that the cells are isolated cells outside of a living organism (e.g. "An isolated eukaryotic cell..."). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-33,37-39,41-44 and 58-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Each of the claims is drawn towards a recombinant DNA molecule comprising an isolated avian lysozyme gene expression control region comprising (a) at least one 5' matrix attachment region, (b) an intrinsically curved DNA region, (c) at least one transcription enhancer, (d) a negative regulatory element, (e) at least one hormone responsive element, (f) at least one avian CR1 repeat element, and (g) a proximal lysozyme promoter and signal peptide-encoding region. As written, the claims encompass either a single lysozyme gene expression control region obtained from a single source (e.g. chicken), or hybrid control regions comprising elements obtained from any source (e.g. a tet operator/repressor binding sequence as a negative regulator obtained from bacteria). In either case, avian sources for such control regions, or elements thereof, include chicken, quail, turkey, goose, duck, pheasant, ornamental birds, ratites, and feral birds. Moreover, several of the claims are directed to "degenerate variants" of the claimed control regions, or elements thereof. The term "degenerate variants" is undefined in the specification and encompasses, at the least, any variation in sequence wherein the control region functions in some manner similar to the described region (i.e. SEQ ID NOS: 65 or 67). Thus, the rejected claims embrace a tremendous number of different lysozyme gene expression control regions, or elements thereof, obtainable from a very large number of different sources.

The instant specification describes the isolation and characterization of an ~12 kb region upstream from the chicken lysozyme gene. Each of the recited elements appears to be described by the instant specification for the chicken lysozyme gene expression control region, comprised within the ~12 kb genomic fragment. However, no means is provided by the instant

specification to envision the nucleotide sequence of such a lysozyme gene expression control region obtained from alternative sources encompassed by the rejected claims (e.g. turkey, turkey vulture, ostrich, etc.). Nor is any basis provided by the specification to envision "degenerate variants" of the control regions described by SEQ ID NO: 65.

The deficiencies of the instant specification are not offset by the teachings of the prior art in that there does not appear to be a description in the prior art of an avian lysozyme gene expression control region comprising each of the elements recited in the rejected claims. Nor is it clear from the prior art that equivalents for each of the recited elements above are even present in, or conserved across, different avian species. Thus, the prior art does not appear to provide a basis for one of skill in the art to envision such control regions in other avians. The prior art does not provide a basis for one to envision degenerate variations in the described sequence (i.e. SEQ ID NO: 65) that function in a similar manner.

Given the broad genus of regulatory sequences embraced by the rejected claims and the lack of a basis in the prior art or instant specification for envisioning specific embodiments other than for the chicken lysozyme gene expression region described in the instant specification, the skilled artisan would not be able to envision additional embodiments of such regions obtained from other sources. Accordingly, the skilled artisan would reasonably have concluded applicant was not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-33,37-39,41-44 and 58-61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 22 are vague and indefinite in that it is unclear whether the term "avian lysozyme gene expression control region" necessarily refers to a regulatory region obtained from a natural source (e.g. chicken, quail, etc), or whether the term encompasses hybrid control regions comprising elements from different sources, including non-avian sources. In other words, does each of elements (a) through (g) have to come from a single source (e.g. chicken), or can they be an amalgam of elements obtained from multiple sources (e.g. a 5' matrix attachment region from the turkey gene, a CR1 element from the chicken, etc.)?

Claims 11, 14, 17, 18, 25, 28, 31, 32, 44 and 61 are vague and indefinite in that the metes and bounds of the term "degenerate variant" are unclear. The term is not explicitly defined in the instant specification and is subjective in nature. For example, even if one accepts that the term means that the variant is functionally similar to its reference sequence, which is not conceded here, how functionally similar does it have to be? What degree of similarity of expression pattern and/or strength, for example, would be required for a sequence to be a "degenerate variant" of SEQ ID NO: 65?

Claims 8 and 22 recite the limitation of an "intrinsically curved" DNA region. This term does not appear to be explicitly defined in the specification or prior art. How "curved" does the DNA have to be in order to satisfy this limitation? Is there a functional definition (e.g. prevents binding of matrix proteins within a region) that is applicable and art recognized for the term?

Claim 21 is vague and indefinite in that it recites the limitation "wherein the recombinant DNA molecule is a virus". It is unclear how a DNA molecule can be a virus, which comprises additional elements than just DNA (e.g. capsid proteins, envelope, etc.). It appears applicants may intend that the recombinant DNA molecule is comprised within a virus, or that the origin of replication recited in claim 19 is obtained from a virus. It would be remedial to amend the claim language to clearly indicate the relationship between the DNA molecule and the recited virus.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PATENT EXAMINER

Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
May 5, 2003